PASCAL MEDICAL

DEC 28 1999

K991562

Confidential	Filename Meniett 20 510(k) Supplement	FDA No. K991562	Date September 15th, 1999

SECTION XVII 510(K) SUMMARY

510(K) Summary

Submitter: **Pascal Medical AB**

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Date prepared: March 31, 1999

Device name: Pascal Medical AB Meniett 20

Classification name: Tympanometer

Predicate Devices: American Electromedics Corporation Screening Tympanometer (K822475) & Hyper/Hypo baric Chambers

This medical device is being submitted in this 510(K) Notification by virtue of the fact that it is substantially equivalent to hypo / hyperbaric pressure chambers which have been used previously for the treatment and temporary relief of symptoms associated with Meniere's Disease. The Meniett 20 is a device which functions in a range of performance specifications which are similar to a conventional tympanometer and is used in a manner similar to a hypo / hyper baric pressure chamber to create localized overpressure in the middle ear to relieve the symptoms associated with Meniere's Disease.

Device Description:

Meniett 20 is indicated for symptomatic treatment of Menière's Disease. The therapeutic effect of Meniett 20 is achieved by applying low frequency, low amplitude pressure pulses to the middle ear whereby inner ear endolymphatic fluids are assumed to be evacuated from the cochlea and thus relieve the patient of the symptoms associated with endolymphatic hydrops.

Patient treatment

The treatment consists of two phases:

1. *Myrongotomy*
   A surgical intervention whereby a conventional ventilation tube is surgically placed in the eardrum of the ear to be treated. This intervention is performed in exactly the same way and using the same materials as for other indications, e.g. otitis media.

2. *Application of pressure pulses to the middle ear*
   The therapy starts after the ventilation tube has been placed in the eardrum. The patient is instructed in how to place the ear-cuff in the external ear canal to minimize leakage to the outer environment. The patient is instructed to treat him/herself three times daily, morning, midday and evening and for three minutes each time. The total daily exposure of pressure pulses in the range of 10-16 mbar with this dosage is 64.8 seconds. Alteration of the standard dosage may be done in after consultation with the treating doctor.

The treatment is continued for as long as the patient finds him/herself in a period of attacks of vertigo. During periods of remission there is no need for treatment

Meniett 20 is an electronically controlled membrane pump. Meniett 20 generates dynamic pressure and consists of a pump house, electronic hardware, software and encapsulation. In connection with the pump house there is a tube to which an ear cuff is connected and through which air pressure pulses from Meniett 20 are transferred to the patient's ear canal. The construction is encapsulated in a plastic cover designed specially for Meniett 20. There is an opening for replacing the battery. With the help of a pulse shape selector, concealed in the battery compartment, there is a possibility to switch between three different pulse shapes. To start and stop the treatment there is an on/off button on the front panel. On the front panel are four indicators for communication with the patient.

Intended Use:

Meniett 20 is indicated for symptomatic treatment of Menière's disease. The therapeutic effect of Meniett 20 is achieved by applying low frequency, low amplitude pressure pulses to the middle ear whereby inner ear endolymphatic fluids are assumed to be evacuated from the cochlea and thus relieve the patient of the symptoms associated with endolymphatic hydrops.

Technological Characteristics:

Comparing the proposed device to the predicate devices, both devices utilize the same range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was performed to evaluate / assess the product life, presentation of data, environmental parameters, power supply and battery life, sound levels, and environmental operating temperatures. The results of these tests confirmed that the proposed device meets the specifications for these parameters.

Clinical Test Results:

20 patients with a definite history and diagnosis of Meniere's disease and active vestibular symptoms have been treated with middle ear pressure pulses using Meniett daily for a period of four weeks. Thereafter, the majority of patients have continued treatment up to 4 months. The dosage was standardized in all patients. The aim of treatment was to relieve patients from the attacks of vertigo and to improve balance and functionality. The results showed that the use of Meniett 20 gave the intended clinical effect in all the patients except two. None of the patients became worse while using Meniett 20. No other adverse effects of treatment have been observed in connection with the use of Meniett 20. Temporary relapses of symptoms have been observed in patients who were not able to continue the use Meniett 20. The symptoms were relieved again in these patients by a renewal of treatment with the Meniett 20. It was demonstrated that the Meniett 20 performed well under the normal conditions of daily clinical use.

Conclusions:

Testing performed on the Pascal Medical AB Meniett 20 indicates that it is safe, effective, and performs as intended, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1999

Jeffrey R. Sideman
Pascal Medical AB
7307 Glouchester Drive
Minneapolis, Minnesota 55435

Re: K991562
Trade Name: Meniett 20
Regulatory Class: Class II
Product Code: 77ETY/874.1090
Dated: September 24, 1999
Received: September 29, 1999

Dear Mr. Sideman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K991562

Device Name: Pascal Medical AB Meniett 20

Indications For Use:

PASCAL MEDICAL

Pre-Market Notification

Pascal Medical AB Meniett 20

SECTION XII INDICATIONS FOR USE STATEMENT

Meniett 20 is indicated for symptomatic treatment of Menière's disease. The therapeutic effect of Meniett 20 is achieved by applying low frequency, low amplitude pressure pulses to the middle ear whereby inner ear endolymphatic fluids are assumed to be evacuated from the cochlea and thus relieve the patient of the symptoms associated with endolymphatic hydrops.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ellsworth L Thompson

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991562

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)